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APPLICATION NUMBER FIRST NAMED APPLICANT ATTORNEY DOCKET NO. FILING DATE 09/320,713 05/27/99 EBNER PF470 EXAMINER HM12/0321 JOSEPH J KENNY PAPER NUMBER AGENT FOR APPLICANTS HUMAN GENOME SCIENCES INC 1647 9410 KEY WEST AVENUE DATE MAILED: ROCKVILLE MD 20850 03/21/01 This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS **OFFICE ACTION SUMMARY** Responsive to communication(s) filed on _ ☐ This action is FINAL. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 D.C. 11; 453 O.G. 213. A shortened statutory period for response to this action is set to expire ______ _ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). **Disposition of Claims** 5,27,29,37-40,44,46,50-155 is/are pending in the application. Claim(s) Of the above, claim(s) is/are withdrawn from consideration. Claim(s) is/are allowed. ☐ Claim(s) ☐ Claim(s) _ is/are objected to. IX Claims 1,25,27,29,37-40,44,46,50-155 are subject to restriction or election requirement. **Application Papers** ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. is/are objected to by the Examiner. ☐ The drawing(s) filed on _ _ is \square approved \square disapproved. ☐ The proposed drawing correction, filed on ___ The specification is objected to by the Examiner. ☐ The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received. ☐ received in Application No. (Series Code/Serial Number) received in this national stage application from the International Bureau (PCT Rule 17.2(a)). *Certified copies not received: _ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). Attachment(s) ☐ Notice of Reference Cited, PTO-892 ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). ___ ☐ Interview Summary, PTO-413 ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

☐ Notice of Informal Patent Application, PTO-152

Part III: Detailed Office Action

Restriction Requirement:

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Applicants election of Invention II, now represented by claims 50-155 in paper number 8 filed 2/8/01, with traverse, is acknowledged. The traversal is on the ground(s) that the examination of the entire application would not constitute a burden to search. This is not found persuasive because contrary to applicants' assertion that any search of the prior art in regard to group II will reveal whether any prior art exists as to the other Groups, a search is directed to references which would render the invention obvious, as well as references directed to anticipation of the invention, and therefore requires a search of relevant literature in many different areas of subject matter.

Applicants newly filed claims are drawn to numerous patentably distinct nucleic acid sequences. Thus, further restriction within the formerly presented Invention II is required, as follows:

The claims are drawn to numerous patentably distinct nucleic acids, each of which constitutes a patentably distinct product. Applicant is required to elect a single invention of a nucleic acid, selected from the group consisting of (i.e. elect one from the following Markush group): a nucleic acid comprising a polynucleotide encoding a protein selected from the group consisting of the following regions of SEQ ID NO:4. Residues 1-160, 10-160, 28-160, 1-150, 1-140, 28-129, 57-64, 72-77, 99-105, 121-128, 19-27, 30-38, 40-48, 58-67, 105-113, 129-137, 151-159, (57-64 and 151-159) (as in claim 104), a single ultimate species from one of (1-28)-160, 1-(129-160), or (1-28)-(129-160), or a single ultimate species of a fragment of residues 1-160 which retains function (as in claim 103), a fragment of \geq 30 nucleotides of SEQ ID NO: 3, and a nucleic acid which hybridizes to the complement of nucleotides 1-860 of SEQ ID NO: 3.

Applicants should note that in some cases multiple claims encompass one of the patentably distinct inventions set forth herein, for example it is presumed by the Examiner in setting forth this requirement that the nucleic acid of ATCC deposit 209665 is SEQ ID NO: 3. To be fully responsive

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to this requirement, Applicants are required to point out which claims correspond to the elected invention.

Although the classifications for these various nucleic acids are overlapping, for instance 536/23.1, each represents a patentably distinct product with distinct physical and functional characteristics. Further the search for more than one product would be burdensome, because each is claimed not by nucleic acid sequence, but by the sequence of the protein encoded thereby, and requires a search of the corresponding region of SEQ ID NO: 1 as well as a 'reverse translation' search of the corresponding region of SEQ ID NO: 2, such that each individual sequence requires two sequence searches which are not required for any of the other sequences, or alternatively by virtue of comprising only a small portion of a disclosed nucleic acid, which requires a separate "word search" of the nucleic acid databases, or by claiming nucleic acids which 'hybridize' to a disclosed nucleic acid, which requires a broader search of the nucleic acid databases. Due to the use of 'comprising' language, it cannot even be said that the search for nucleic acids encoding amino acids 1-160 of SEQ ID NO: 4 would reveal art pertaining to, for instance a nucleic acid *comprising* a region encoding amino acids 19-27 of SEQ ID NO: 4, as the latter could be found embedded in a completely different protein. Accordingly, restriction is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 37 C.F.R. § 1.48(b) and by the fee required under 37 37 C.F.R. § 1.17(i).

Advisory Information:

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Serial Number 09/320713 Art Unit 1647

Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 305-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. **Please** advise the Examiner at the telephone number above when an

informal fax is being transmitted.

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Lorraine Spector, Ph.D.
Primary Examiner

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